IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF NEBRASKA

CONNIE M. BROOKS, Plaintiff, v. NEBRASKA BY-PRODUCTS, INC., and BLUE CROSS BLUE SHIELD OF NEBRASKA, Defendants.	)	8:06CV309 MEMORANDUM OPINION

This matter is before the Court on cross motions for summary judgment filed by both the plaintiff, Connie M. Brooks ("Brooks")(Filing No. 31) and the defendants, Nebraska By-Products, Inc. and Blue Cross Blue Shield of Nebraska ("Blue Cross")(Filing No. 28). Brooks' second amended complaint ("SAC") asserts two causes of action (Filing No. 11). The parties have resolved the second claim (See Filing No. 35, Joint Stipulation for Dismissal of Plaintiff's Second Cause of Action), leaving a single remaining claim. Brooks' remaining claim seeks coverage for two medications prescribed by her physician: Heparin Troches, an oral compound for a blood clotting disorder, and Stadol NS ("Stadol"), a pain medication (SAC, ¶ 12). While Blue Cross has approved Stadol for Brooks, it has limited its coverage to a maximum of 9 canisters 10 mg/ml per month. Brooks seeks coverage for a an additional 21 canisters per month for a total of 30 per

month (SAC, ¶ 12). Brooks brings this action under the Employment Retirement Security Act of 1974 ("ERISA") § 1132(a)(1)(B). Brooks also seeks her reasonable attorney's fees and costs under ERISA § 1132(g)(1). Blue Cross asserts that its denial of benefits was proper under the prescription drug benefit coverage under the group contract. The Court has reviewed the motions, briefs and the applicable law and makes the following findings.

I. Background

Nebraska By-Products, Inc. ("Nebraska By-Products") is a Nebraska corporation and is a sister organization to defendant Great Plains Sales, Inc. ("Great Plains Sales"). Plaintiff Connie Brooks' husband, Paul Brooks, was employed by Great Plains Sales.

Nebraska By-Products established an insured employee group health plan underwritten by Blue Cross, which is governed by the terms and conditions of the "Blue Preferred, Preferred Provider Organization Master Group Contract for Employers and Associations" ("Group Contract") (Ex. 2: Affidavit of Yolanda Belman & attached Ex. A ("AR"), which includes the following: Master Group Applications for the years 2004, 2005, and 2006: AR 1-145; Group Contract: AR 146-219; A Guide to Your Blue Preferred Health Benefits: AR 567). The employees of Great Plains Sales and their eligible dependents are eligible for coverage under the

Group Contract. Paul Brooks completed a group enrollment form for his family in June 2004, and at all relevant times, Brooks was eligible for prescription drug benefits pursuant to the terms, conditions, and limitations of the Group Contract. Each year Blue Cross provided Paul Brooks with a Schedule of Benefits, a written booklet entitled "A Guide to Your Blue Preferred Health Benefits," and materials relating to prescription drug benefits.

B. Plaintiffs Benefit Claim for Stadol Nasal Spray

In August 2004, one of Brooks' physicians, Scott M. Ehresman, M.D., sought preauthorization for 30 canisters 10 mglml per month of Stadol. A Blue Cross physician consultant reviewed the request and concluded that Stadol was not "medically necessary" at the dosage prescribed (AR 453-54). Thus, Blue Cross denied the request for 30 canisters of Stadol per month, but approved nine canisters per month. *Id.* Dr. Ehresman and plaintiff were informed of Blue Cross's decision in a letter dated August 20, 2004 (AR 453-54, 465-66).

In October 2004, Dr. Ehresman and Joseph H. Brewer, M.D., a doctor who has treated Brooks since 1990, both submitted letters to Blue Cross appealing the decision denying benefits for 30 canisters of Stadol per month (AR 468-70). Doctors Ehresman and Brewer opined that Brooks requires pain medication because she suffers from chronic pain, fibromyalgia, chronic fatigue syndrome and chronic Lyme disease. *Id*. Blue Cross also received

an incomplete set of documents from Bristol-Myers Squibb Company regarding Stadol NS, and what plaintiff purports to be a 2003 letter from Principal Financial, one of her previous insurers, approving 30 canisters of Stadol per month (AR 471-78).

The appeal was handled as a First Level Appeal. An independent physician reviewer, K. Coughlin, M.D., upheld the benefit limitation of nine canisters of Stadol per month, concluding: "the use of Stadol at this level [30 canisters per month] is outside the standard of care. While it may be supported by the two physicians appealing, use of Stadol at this level is not supported in the literature and is prone to dependence. Dosing at this level cannot be supported by authorizing benefits to cover." (AR 480-89). Brooks, Dr. Ehresman and Dr. Brewer were informed of this decision in a letter dated October 22, 2004 (AR 480-81).

In November 2004, Brooks requested a Second Level Appeal (AR 488-89). Brooks and her husband appeared in person before the Second Level Grievance Panel (AR 501). The three-member panel, which included an independent medical doctor and an independent registered nurse, reviewed the documentation submitted by Brooks and reviewed her medical records (AR 496-514). The panel upheld the benefit limitation of nine canisters of Stadol per month, finding "the amount of Stadol used [i.e. 30 canisters per month] is well above the recommended treatment and

outside the normal standard of care. Use in this amount raises grave concerns with addiction. Alternative treatments should be considered." (AR 501). Blue Cross informed Brooks of this decision in a letter dated December 1, 2004 (AR 496-99).

On December 7, 2004, Brooks filed a complaint with the Nebraska Department of Insurance complaining about Blue Cross's denial of benefits for 30 canisters per month of Stadol (referred to hereafter as the "Stadol Complaint")(AR 517-20). The Stadol Complaint included correspondence from Brooks, Brooks' daughter and from Doctors Brewer and Ehresman (AR 516-28). Upon receipt of the Stadol Complaint, Blue Cross requested another independent medical doctor review Brooks' request for 30 canisters per month of Stadol. The physician reviewer noted that the "medical record appears to show ongoing pain and disability despite 30 canisters per month. The failure of this regimen is consistent with drug tolerance and dependence. The medical literature, manufacturer recommendations, and standard of medical practice would not support more than 9 canisters per month in this case" (AR 534). Blue Cross responded to the Stadol Complaint in writing on January 11, 2005 (AR 529-34).

C. Brooks's Benefit Claim for Heparin Troches

Brooks submitted benefit claims for Heparin tablets, a compound oral medication also known as Heparin Troches ("Heparin Tablets") on July 19, 2004, and August 24, 2004 (AR 360-63).

Initially, Blue Cross denied benefits for the reason that Heparin Tablets are not an FDA-approved drug (AR 399-400). On November 22, 2004, Blue Cross received a letter from Brooks appealing the denial (AR 373). Brooks' appeal included information stating that Heparin is an FDA-approved drug (AR 374-78). The appeal was handled as a First Level Appeal, and as part of the appeal process, the benefit denial was reviewed by Blue Cross's Pharmacy Director, Lee Handke, Pharm.D. (AR 372). Dr. Handke noted that although Heparin is an FDA-approved prescriptive ingredient used in making the compound, Heparin is recommended to be given by intermittent IV injection, continuous IV infusion or by deep subcutaneous injection. *Id*. There is no credible evidence to indicate receiving a compound oral formulation (i.e. a tablet) is an appropriate route of administration for Heparin. *Id*. According to the American Hospital Formulary Service Drug Information Reference, "Heparin is not absorbed from the GI tract and must be administered parenterally." *Id*. Dr. Handke further noted that there are commercially available anti-coagulant oral products that may be suitable alternatives to oral Heparin. *Id*. Thus, in Dr. Handke's opinion, Heparin Tablets are an investigative treatment. *Id.* Coverage for investigative drugs is excluded under the Group Contract (AR 618-19, 621-22). Accordingly, the denial of benefits for Heparin Tablets was

upheld, and Brooks was notified of Blue Cross' decision in a letter dated December 17, 2004 (AR 366-69).

Sometime in January 2005, Brooks sought assistance from the Nebraska Department of Insurance with regard to Blue Cross' denial of benefits for Heparin Tablets (referred to hereafter as the "Heparin Complaint")(AR 391-97). Upon receipt of the Heparin Complaint, Blue Cross sought the opinion of an independent medical doctor (AR 387). The physician reviewer upheld the denial on the grounds that administration of Heparin orally in tablet form is investigative and lacks “any proven validity.” *Id*. The physician reviewer noted, the actual denial reason was "investigative" and not "lack of FDA-approval." *Id*. Blue Cross responded to the Heparin Complaint by written letter to the Nebraska Department of Insurance on February 14, 2005 (AR 399-402).

In September 2005, Brooks' attorney requested a second appeal (AR 407). Blue Cross sought medical records from Doctors Ehresman and Brewer which were reviewed by the Second Level Appeal Panel (AR 410-50). The Second Level Appeal Panel upheld the denial, determining that Heparin Tablets are investigative (AR 408). Brooks and her attorney were informed of this decision by letter dated September 28, 2005 (AR 403-06).

II. Legal Analysis

A. Summary Judgment

Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories and admissions on file, together with any affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The party moving for summary judgment must always bear "the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *see* NELR 56.1(a). When the party seeking summary judgment carries its burden, the opposing party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The opposing party "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1996); *see* NELR 56.1(b).

As always at the summary judgment stage, the evidence is viewed in a light most favorable to the nonmoving party, with all inferences drawn in that party's favor. *See Matsushita Elec.*

Indus., 475 U.S. at 587. In making this review, the Court is particularly aware that it does not "weigh the evidence and determine the truth of the matter" but instead determines "whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249.

B. Standard of Review

A denial of benefits challenged under § 502(a)(1)(B) is reviewed under a *de novo* standard unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan. *Firestone Tire & Rubber v. Bruch*, 489 U.S. 101, 115 (1989). When a plan gives discretion to the plan administrator, then a plan administrator's decision is reviewed judicially for an abuse of discretion. *Id*. Under an abuse of discretion standard of review, a plan administrator's decision will stand if reasonable; "i.e., supported by substantial evidence." *Fletcher-Merrit v. Noram Energy Corp.*, 250 F.3d 1174, 1179 (8th Cir. 2001)(*quoting Donaho v. FMC Corp.*, 74 F.3d 894, 899 (8th Cir. 1996)). "Substantial evidence . . . means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Fletcher-Merrit*, 250 F.3d at 1179 (*quoting Consol. Edison Co. of New York v. NLRB*, 305 U.S. 197 (1938)).

"In this circuit, when an insurance policy is the ERISA plan, the abuse-of-discretion standard applies only if the policy

contains 'explicit discretion-granting language.'" *Walke v. Group Long Term Disability Ins.*, 256 F.3d 835 (8th Cir. 2001) (*quoting Bounds v. Bell Atlantic Enter. F.L.T.D. Plan*, 32 F.3d 337, 339 (8th Cir. 1994). The language found in the Blue Cross policy at issue states: "The Group Applicant grants to Blue Cross and Blue Shield of Nebraska discretionary authority to determine eligibility for benefits and to construe and interpret the terms of the Plan, consistent with the terms of this Contract" (AR 208). Thus the Court finds that the proper standard of review is for abuse of discretion because the policy contains "explicit discretion-granting language."

III. Discussion

In considering whether Blue Cross abused its discretion, "we must affirm if a reasonable person could have reached a similar decision, given the evidence before him, not that a reasonable person would have reached that decision." *Groves v. Metro. Life Ins. Co.*, 438 F.3d 872, 875 (8th Cir. 2006) (internal quotation omitted). The essence of the inquiry is whether the decision is supported by substantial evidence. *See McGee v. Reliance Standard Life Ins. Co.*, 360 F.3d 921, 924 (8th Cir. 2004)(noting that a reasonable decision is one supported by substantial evidence). We consider "both the quantity and quality of evidence" in determining whether substantial evidence supports the decision to deny benefits. *Groves*, 438 F.3d at 875.

Substantial evidence is "more than a scintilla, but less than a preponderance." *Ferrari v. Teachers Ins. & Annuity Ass'n*, 278 F.3d 801, 807 (8th Cir. 2002) (internal quotation omitted).

Applying this deferential standard of review, we conclude substantial evidence supports Blue Cross' denial of benefits as proper under the prescription drug benefit coverage under the group contract. The policy specifically stated that "[a]ll services must be medically necessary and Scientifically Validated in order for benefits to be payable." (AR 194). If a drug has not been scientifically validated, it is considered investigative. *Id*. The policy then defines "investigative," setting out a five-factor test. *Id*. One factor is that "[e]vidence must permit conclusions concerning the effect of the technology [drug] on health outcomes." *Id*. "The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the results are considered in evaluating the evidence." *Id*. Blue Cross will determine whether a drug is investigative. *Id*.

Heparin Troches

The record does not contain any evidence, beyond the assertion by Brooks' own physician to support the use of Heparin in an oral tablet form. Brooks does not direct the Court to any information and nothing suggests that Blue Cross, or any of the

appeal panels, possessed any scientifically validated studies to support the use of Heparin Troches to treat Brooks' condition. In fact, the physician reviewer upheld the denial on the grounds that administration of Heparin orally in tablet form is investigative and lacks "any proven validity" (AR 387).

Conversely, there was ample evidence that the recognized delivery method for Heparin is by intermittent IV injection, continuous IV infusion or by deep subcutaneous injection (AR 372). Thus, substantial evidence supports the decision by Blue Cross to deny coverage for Heparin Troches. Therefore, the Court will grant defendants' motion for summary judgment and deny plaintiff's motion for summary judgment as to this claim.

Stadol

At issue here is not whether Stadol is covered, but whether Stadol is covered in the quantity sought by Brooks. Blue Cross points to substantial evidence supporting a limit on the quantity of Stadol prescribed to no more than 9 canisters per month. An independent physician reviewer, K. Coughlin, M.D., upheld the benefit limitation of nine canisters of Stadol per month, concluding: "the use of Stadol at this level [30 canisters per month] is outside the standard of care. While it may be supported by the two physicians appealing, use of Stadol at this level is not supported in the literature and is prone to

dependence. Dosing at this level cannot be supported by authorizing benefits to cover." (AR 480-86). Dr. Coughlin's opinion was supported at the second level of appeal where the appeal panel upheld the benefit limitation of nine canisters of Stadol per month, finding "the amount of Stadol used [i.e. 30 canisters per month] is well above the recommended treatment and outside the normal standard of care. Use in this amount raises grave concerns with addiction. Alternative treatments should be considered." (AR 501). The opinions of Dr. Coughlin and the second level appeal panel constitute substantial evidence in support of the decision by Blue Cross.

Brooks points to no evidence, other than the opinions of her treating physicians, to support prescribing Stadol at levels over three times above the recommended dosage. A treating physician's opinion is not entitled to special deference. *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 825 (2003). Even if the Court were to give special consideration to the opinions of Brooks' doctors, it would not change the fact that the decision by Blue Cross is supported by substantial evidence. The Court finds that the benefit decision of Blue Cross, limiting the covered quantity of Stadol to no more than 9 canisters per month, was not an abuse of discretion. Therefore, the Court will grant defendants' motion for summary judgment and deny plaintiff's motion for summary judgment as to this claim.

A separate order will be entered in accordance with this memorandum opinion.

DATED this 13th day of April, 2007.

BY THE COURT:

/s/ Lyle E. Strom

LYLE E. STROM, Senior Judge
United States District Court